

REMARKS

I. Status of the Claims

Claims 14-23 and 26-29 are pending. No amendments are made herein.

II. Rejection Under 35 U.S.C. § 103(a)

The Examiner rejects pending claims 14-23 and 26-29 as allegedly obvious over U.S. Patent No. 4,185,106 ("Dittmar") in view of an article by Hanel et al. (*Mycoses* 34 (Supp) 1:91-93 (1991)) ("Hanel") and a "medical dictionary" or U.S. Patent No. 5,834,409 ("Ramachandran") "if necessary." Final Office Action at 3. In this rejection, the Examiner continues to use Dittmar as the primary reference, but now matches Dittmar with new secondary references. According to the Examiner, Dittmar allegedly teaches an antidandruff treatment using a pharmaceutical composition containing 1-hydroxy-2-pyridones, such as ciclopirox, as active agents. *Id.* at 3-4. The Examiner also contends that Dittmar teaches a "weakly acidic composition which is desirable for hair composition[s]" *Id.* at 5. The Examiner acknowledges that Dittmar does not teach the use of this composition for treating seborrheic dermatitis. *Id.* at 4.

In an effort to fill this gap, the Examiner relies on Hanel. Hanel allegedly teaches that an antimycotic agent such as 1-hydroxy-2-pyridone, for example ciclopirox, was effectively used to treat seborrheic eczema in humans. *Id.* According to the Examiner, Hanel also allegedly teaches "significant therapeutic effectiveness" that is achieved by using ciclopirox where "strong inhibition of inflammation and infiltration and flakiness" was obtained. *Id.* Relying on excerpts from on-line medical dictionaries, the Examiner then asserts that seborrheic eczema is an alternative term for seborrheic dermatitis. *Id.*

Taking these references in combination, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to extend the alleged teachings of Dittmar to include seborrheic dermatitis. *Id.* at 4. She alleges that the skilled artisan would have been motivated to combine Dittmar, Hanel, and the cited “medical dictionary” and make the modification because these references are “drawn to the same technical fields [(] constituted with same ingredients and share common utilities” and are “pertinent to the problem which applicant concerns about.” *Id.* at 5.

Applicant respectfully traverses the rejection for reasons of record with respect to Dittmar, and for the following additional reasons.

A. *The Examiner has not made a Prima Facie Case of Obviousness*

Based on her research of electronic medical dictionaries, the Examiner suggests that seborrheic eczema is an alternative term for seborrheic dermatitis and tries to use this to relate the proposed combination of Dittmar and Hanel to the present claims. Applicant disagrees with the Examiner and submit that she has not made a *prima facie* case of obviousness as discussed below.

1. There would have been no motivation for one of ordinary skill in the art to combine Hanel And Dittmar.

One of the requirements for a *prima facie* case of obviousness is that there be some suggestion or motivation in the references to modify or combine their teachings. M.P.E.P. §2143. This requirement also has not been met here. Specifically, nothing in the references cited by the Examiner equates dandruff (as in Dittmar) and seborrheic eczema (as in Hanel), or offers any suggestion or motivation to modify Dittmar’s treatment of dandruff for use in treatment of seborrheic dermatitis.

Assuming *arguendo* that seborrheic eczema and seborrheic dermatitis were equivalents, one of ordinary skill in the art would find no teaching, suggestion or motivation to modify Dittmar for the treatment of seborrheic dermatitis. As Applicant already noted, Dittmar teaches the treatment of dandruff. The declaration of Dr. Mitchell Wortzman, filed on September 7, 2006, clearly distinguishes dandruff from seborrheic dermatitis. Dandruff is a "noninflammatory scaling of the scalp," and seborrheic dermatitis is an "inflammatory, erythematous, and scaling eruption." Wortzman Declaration at page 2. In addition, the scales of dandruff look different from the scales of seborrheic dermatitis. *Id.* Thus, because seborrheic dermatitis and dandruff are different conditions, as clearly shown by this evidence of record, the skilled artisan would not have been motivated to modify or combine the teachings of Dittmar relating to dandruff with the teachings of Hanel relating to seborrheic eczema.

In order to justify an obviousness rejection, the Examiner must provide "clear and particular" evidence of suggestion or motivation to combine the prior art references. *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999). In this case, the Examiner has not set forth any evidence, let alone "clear and particular" evidence, to substantiate the proposed modification. Therefore, the §103 rejection must be removed for at least this reason.

2. Obvious to try is not the standard for §103.

As discussed above, there is no teaching, suggestion or motivation to modify and combine Dittmar (for dandruff) and Hanel (for seborrheic eczema) to obtain a method of treatment for seborrheic dermatitis. At best, it may have been obvious to one of ordinary skill in the art to try the antidandruff method of Dittmar on patients with

seborrheic eczema. Even if one assumes that seborrheic eczema is synonymous with seborrheic dermatitis, obvious to try is not the standard for §103. A determination of obviousness simply cannot be based on what the skilled person might try or find obvious to try. Rather, the proper test considers what the prior art would have actually led one of ordinary skill to do. See *In re O'Farrell*, 853 F.2d 894, 7 U.S.P.Q.2d 1673 (Fed. Cir. 1988).

Thus, in view of the above, the Examiner has not established a *prima facie* case of obviousness. In order to establish a *prima facie* case, the Examiner "bears the initial burden of factually supporting any *prima facie* conclusion of obviousness." See *In re Fine*, 837, F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988). The Examiner has not met that burden here. Therefore, Applicant requests that the Examiner withdraw this rejection.

B. Discussion of Telephonic Interview

In addition to the arguments above, Applicant would like to thank the Examiner for the telephonic interview of December 6, 2006, at which time possible amendments to the pending claims were discussed. Applicant did not receive an interview summary from the Examiner and so, as required by M.P.E.P. § 713.04 ("[a] complete written statement as to the substance of any . . . electronic mail or telephone interview with regard to the merits of an application must be made of record in the application . . ."), Applicant discusses below for the record this interview and subsequent e-mail communication from the Examiner.

During the telephonic interview of December 6, 2006, the Examiner proposed an amendment to claim 14 that, in the Examiner's opinion, would render claim 14

allowable. On December 7, 2006, the Examiner sent an e-mail (attached as Exhibit A) to Applicant's representative, Carol P. Einaudi, setting forth the suggested amendment and the Examiner's rationale for suggesting the amendment. Specifically, the Examiner suggested amending claim 14 as follows:

(B) ~~at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants;~~
~~wherein the composition has a pH ranging from about 4.5 to about 6.5; and~~
~~wherein the composition is a single composition~~ an anionic surfactant as a base surfactant with anphoteric surfactant as cosurfactant; wherein the composition has a pH ranging from about 4.5 to about 6.5; and wherein the composition is in the form of shampoo and the said 1-hydrdoxy-2-pyridone is 1-hydroxy-4-methyl-6-cyclohexyl-2(1H) pyridine.

In making her proposal, the Examiner relied on five items to support non-obviousness:

(1) a description of Stieprox® Shampoo taken from a consumer medical information website submitted in the IDS filed September 22, 2006, and showing that Stieprox® Shampoo contains anionic (sodium laureth sulphate) and amphoteric (cocamidopropyl betaine) surfactants; (2) a citation from the website www.pharmacychecker.com, which incorrectly states that Loprox® Shampoo and Stieprox® Shampoo (in Canada) have the same formula; (3) Example 2 of the instant specification, showing a shampoo containing ciclopirox, an anionic surfactant, and an amphoteric surfactant; (4) a teaching in the specification at page 6 of the "importance" of amphoteric surfactants "for the optimization of" anionic surfactants; and (5) Applicant's statements on the commercial success of Loprox® Shampoo, particularly at page 13 of the Supplemental Response filed September 22, 2006, and the Declaration of Mr. Kevin Kriel.

The Examiner, in her e-mail of December 7, 2006, acknowledged the unexpected commercial success of the use of Loprox® Shampoo ("Loprox has unexpected commercial success."). The Examiner, however, incorrectly assumed that Stieprox® Shampoo (which is sold in Canada for use in the treatment of seborrheic dermatitis) was Applicant's commercial embodiment. As explained below, in fact, Stieprox® Shampoo contains different surfactants than are used in Loprox® Shampoo. The use of both products to treat seborrheic dermatitis falls within the scope of the pending claims.

The pending claims cover the use of a specific 1-hydroxy-2-pyridone with any combination of four (4) types of surfactants to treat seborrheic dermatitis. Loprox® Shampoo contains ciclopirox and a combination of nonionic and anionic surfactants. (Attached as Exhibit B is a copy of the Loprox® Shampoo insert.) Stieprox® Shampoo contains ciclopirox and a combination of anionic and amphoteric surfactants. Both products, when used to treat seborrheic dermatitis, are within the scope of the invention and the pending claims. As the Examiner acknowledged, the use of Loprox® Shampoo and seborrheic dermatitis is commercially successful. The use of Stieprox® Shampoo on seborrheic dermatitis is also commercially successful outside the U.S. (as reflected in the website cited by the Examiner).

Applicant believes that the amended claims proposed by the Examiner would only read on the use of Stieprox® Shampoo and not the use of Applicant's product, the Loprox® Shampoo formulation. Therefore, although Applicant appreciates the Examiner's suggested amendment, the proposed amended claims do not encompass the full scope of their invention, as supported by the evidence of unexpected commercial success.

Therefore, while Applicant reasserts that no *prima facie* case of obviousness has been established, even if one has been established, the rejection has been overcome with evidence of commercial success of two embodiments (the indicated uses of Loprox® Shampoo and Stieprox® Shampoo). Both embodiments are covered by the pending claims, which Applicant respectfully submits, are allowable. For this additional reason, the rejection under §103 should be withdrawn.

III. Conclusion

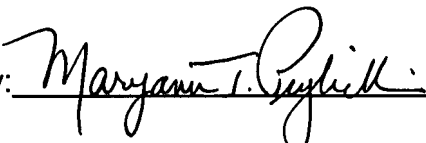
In view of the foregoing remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: April 16, 2007

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